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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/571,512

06/05/2006

Matthew Neil Sarkar

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EXAMINER

STUART, COLIN W

ART UNIT

PAPER NUMBER

3771

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/571,512	Applicant(s) SARKAR ET AL.	
	Examiner COLIN STUART	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/10/06, 9/5/06, & 11/16/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the preliminary amendment filed 3/10/06. Claim 27 has been added, and claim 26 has been cancelled. Currently, claims 1-25 and 27 are pending in the instant application.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "first side" in claim 6 ln. 3, the "discharge port" in claim 12 ln. 4, and the "source" in claim 21 ln. 2 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "29" has been used to designate both the spring and central region and reference character "26" has been used to designate both an exit orifice and diaphragm.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

Art Unit: 3771

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

3. The information disclosure statement filed 3/10/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 21-24 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 16, the language "the valve member" in line 4 is unclear because the examiner cannot positively ascertain the limitations as claimed as there are

Art Unit: 3771

multiple valve members. The examiner is reading this limitation to be directed towards the secondary valve member.

Claim 21 and 23 recites the limitation "the reservoir" in line 3 and line 2 respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Liston (3,537,448).

In regards to claim 1, Liston shows a dry powder inhaler which includes a drug entrainment device 23 and a valve 13 actuable by a user (col. 3 ln. 35-55) to cause pressurized gas to flow through the device and entrain the dose. The valve 13 includes a valve member 83 which is biased in an open and closed position by the pressurized gas either allowing or preventing the flow of gas into the entrainment device (see Fig. 1).

In regards to claim 2, Liston shows a dry powder inhaler with valve 13 and valve member 83 in which the pressurized gas, which is present in both chambers above and below valve member 83, acts on both sides of the valve member 83 (see Fig. 1).

In regards to claim 3, Liston shows a dry powder inhaler which the pressurized gas acts over a larger cross-section of the bottom side (directly adjacent to chamber 87) than the pressurized gas which acts on element 75 which in turn acts on a smaller cross-section (equal to cross-section of element 75) of the valve member 83.

In regards to claim 4, Liston shows a dry powder inhaler which the pressurized gas acting over each side of the valve member 83 is substantially the same when in the closed state. If the pressure on either side were to be substantially different than this would cause a shift from the open to closed state or vice versa.

In regards to claim 5, Liston shows a dry powder inhaler in which the valve member 83 moves from closed state to open state in response to a change in pressure of the gas acting on one side relative to the other side as discussed above.

In regards to claim 6, Liston shows a dry powder inhaler which includes a reservoir (the chamber above the valve member 83) for pressurized gas and a valve orifice 81 for the passage of pressurized gas to the device. The first side of valve member includes the attached element 75 which, through movement of the valve member 83, forms a seal with the valve orifice when in the closed state such that pressurized gas in reservoir only acts on a portion of the first side defined by cross-sectional area of the valve orifice.

In regards to claim 7, Liston shows a dry powder inhaler which includes a tube 77 at the mouth of valve orifice in communication with the reservoir (through conduit 89 and element 93). The tube 77 includes a valve seat where the first side, including attached element 75, forms seal in the closed state.

Art Unit: 3771

In regards to claim 8, Liston shows a dry powder inhaler in which the valve member 83 has pressurized gas acting on the entire first side surface when seal is broken biasing the valve into open position (see Fig. 1).

In regards to claims 9-10, Liston shows a dry powder inhaler which includes a mechanism, in the form of the combination of the spring element 79 (col. 2 ln. 47) the pressurized air surrounding the valve member 83, arranged to bias the valve member into a closed state when pressure in the reservoir is discharged through the valve.

In regards to claims 11-13, Liston shows a dry powder inhaler which includes a mechanism which discharges the pressure that biases valve member 83 into closed state moving it to the open state. The pressure in primary chamber 87 becomes great enough to bias secondary valve 105 such that the pressurized gas escapes through discharge ports 101 and 103 in the atmosphere.

In regards to claim 14, Liston shows a dry powder inhaler in which the discharge port 101 opens to the atmosphere through port 103 via breath actuation valve and opens discharge port allowing escape of pressurized gas to the atmosphere (see col. 3 ln. 35-55).

In regards to claim 15, Liston shows a dry powder inhaler which includes a secondary valve member 95 which is movable in response to inhalation from a closed position into a second open position as claimed. The entire valve structure 13 is responsive to the users breathing efforts.

In regards to claim 16, Liston shows a dry powder inhaler in which the pressure in the primary chamber 87 acts over a smaller cross-sectional area of a first side of the

Art Unit: 3771

secondary valve member, through element 105 connected to secondary valve member 95, than the area of the other side which atmospheric pressure acts on through conduit 109 and port 27 of the device (see Fig. 1).

In regards to claims 17-18, Liston shows a dry powder inhaler which includes a biasing mechanism, spring 107, biasing the secondary valve member into a closed state when pressure in primary chamber has been discharged.

In regards to claim 19, Liston shows a dry powder inhaler in which the secondary valve member 95 is biased in the closed position when pressure acting on either side is substantially the same.

In regards to claims 20 and 25, Liston shows a dry powder inhaler in which the first and secondary valve members are "flexible diaphragm" (col. 3 ln. 29).

In regards to claims 21-22, Liston shows a dry powder inhaler which includes a source of pressurized gas or air (not show) connected to hose 73 which charges both the reservoir and the primary chamber.

In regards to claim 23, Liston shows a dry powder inhaler which includes a conduit 89 which communications the reservoir with the primary chamber via tube 77 and check valve 93.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3771

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 24 and 27 rejected under 35 U.S.C. 103(a) as being unpatentable over Liston (3,537,448) as applied to claim 21 above, and further in view of Armer et al. (6,095,141).

In regards to claims 24 and 27, Liston teaches all the limitations as discussed above but is silent as to specifically stating what the source of pressurized gas entails. However, Armer teaches an apparatus for delivering aerosolized medicine (both dry powder inhaler and metered dose inhaler, Armer col. 1 ln. 19-20) and discloses using "propellant such as ... hydrofluroalkane (HFA)" (Armer col. 1 ln. 28-29) for delivering the medication. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the source of pressurized gas of Liston with the HFA propellant as taught by Armer in order to provide a propellant which is less degrading on the environment such as typical CFCs.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art: Lundin (2002/0017301) and Harvey (7,387,121) relate to dual chambered valve structures and Genosar et al. (6,367,471) relates to using HFA propellant with inhalers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/571,512
Art Unit: 3771

Page 10

/COLIN STUART/
Examiner, Art Unit 3771

/Steven O. Douglas/
Primary Examiner, Art Unit 3771